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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,667	08/02/2007	Verity Dowdell	NV2-019US	2799

959 7590 01/21/2009
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EXAMINER

BAEK, BONG-SOOK

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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01/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,667	Applicant(s) DOWDELL ET AL.	
	Examiner BONG-SOOK BAEK	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 and 29-48 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,23-27,31,32 and 35-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,10-22,29,30,33,34,47 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claim 28 has been canceled and claims 1-27 and 29-48 are currently pending.

Election/Restrictions

Applicants' election of group I and election of the following species: (S)- 4-Fluoro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo [e] [1,4]diazepin-3-yl)-2-piperidin-1-yl- benzamide as a single disclosed species of compounds of formula (I); an adult suffering from immunodeficiency species as a single disclosed species of patient population; and species A comprising a benzodiazepine derivative as a single disclosed species from different medicaments, in the reply filed on 12/15/2008 are acknowledged. Upon reconsideration, the requirement to elect a single disclosed species of patient population is hereby withdrawn.

The election was made with traverse. However, applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, Thus, the restriction and species election are still deemed proper and made final.

Claims 8-9, 23-27, 31-32, and 35-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group or species, there being no allowable generic or linking claim. Claims 1-7, 10-22, 29-30, 33-34, and 47-48 are under examination in the instant office action.

Priority

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The instant application is a 371 of PCT/GB2005/001023 filed on 3/18/2005 and claims benefit of foreign application filed on 3/19/2004. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of foreign application has been submitted on 9/19/2006.

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be 3/18/2005.

Information Disclosure Statement

No information disclosure statement has not been filed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

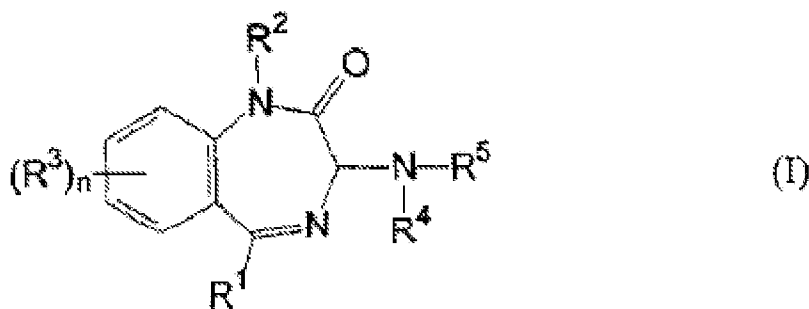
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-7, 10-22, 29-30, 33-34, and 47-48 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 2004/026843 (pub date: 4/1/2004 and filing date: 9/22/2003)

WO 2004/026843 teaches benzodiazepine derivatives of the following formula (I), which encompass compounds generically claimed in the instant claims, especially when R₅ is XR₆ wherein X is CO and R₆ is aryl, aryl-(C₁₋₆ hydroxyalkyl), heteroaryl-(C₁₋₆ hydroxyalkyl), or heterocyclyl-(C₁₋₆ hydroxyalkyl) (abstract).



It further teaches a method for treating a patient suffering from or susceptible to an RSV infection, comprising administering to said patient an effective amount of a compound of formula (I) or a pharmaceutically acceptable salt thereof, which are active against respiratory syncytial virus (RSV) (p1, lines 19-25 and claim 28). Also, it teaches the use of the compound in the treatment of concomitant RSV and influenza infections and in the treatment of human metapneumovirus, measles, parainfluenza viruses and mumps (claims 33-34). In addition, the reference discloses that the compounds of the invention are administered by intranasal or intrabronchial administration (claim 30) and the medicament comprising the compound is typically for use in treating a patient who is a child under two years of age wherein said child

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suffers from chronic lung disease, and for use in preventing RSV infection in an infant less than 6 years of age, who was born after 32 weeks of gestation or less (claims 19-21).

The reference differs from the instant claims insofar as it does not specifically teach the elected compound, (S)- 4-Fluoro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo [e] [1,4]diazepin-3-yl)-2-piperidin- 1-yl- benzamide.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the elected compound, (S)- 4-Fluoro-N-(2-oxo-5-phenyl-2,3-dihydro-1H-benzo [e] [1,4]diazepin-3-yl)-2-piperidin-1-yl- benzamide for treating a patient suffering from or susceptible to an RSV infection as taught by WO 2004/026843 with a reasonable expectation of success because of the following reasons: WO 2004/026843 already disclosed benzodiazepine derivatives, which have the same core structure as the elected species, with various substituents at R₆ position (R₅ position of the formula (I) in the instant application) while retaining the same anti-RSV activity. One of ordinary skill in the art at the time the invention was made would have expected that the elected species would function similarly to the compounds of WO 2004/026843, which are known to be active against RSV, since they have the same core structure and functional group although there is a little difference in the substitution of the phenyl ring (R₅ position of the formula (I) in the instant application). Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to try the elected compound for a patient suffering from or susceptible to RSV infection as taught by WO 2004/026843 on the expectation that structurally similar compounds would possess similar properties and because it is routine nature to perform such experimentation in the art of 10593667 medicinal chemistry.

Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claim 1-7, 10-22, 29-30, 33-34, and 47-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36-38 of copending Application No. 10/593382 or claims 36-38 of copending Application No. 10/593666. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '382 and '666 applications are drawn to a method for treating RSV infection in a patient with the same compounds as recited in the instant application. Although the instant claims do not recite an RSV fusion protein which is recited in the claims of '382 and '666 applications, the instant claims recite the open language "comprising", which does not exclude additional unrecited elements (see MPEP 2111.03).

This is a provisional obviousness-type double patenting rejection.

Claim 1-7, 10-22, 29-30, 33-34, and 47-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/528250 (371 application of WO 2004/026843). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '250 application are drawn to a method for treating a patient suffering from or susceptible to an RSV infection with the benzodiazepine derivatives of the same core structure as recited in the instant claims. As stated above in the 103 rejection, one of ordinary skill in the art at the time the invention was made would have expected that the compounds of the instant claims would function similarly to the compounds of '250 claims, which are known to be active against RSV, since they have the same core structure and functional group with a little difference in the substitution of the phenyl ring (R₅ position of the formula (I) in the instant application).

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Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to try the compounds of the instant claims for a patient suffering from or susceptible to an RSV infection on the expectation that structurally similar compounds would possess similar properties and because it is routine nature to perform such experimentation in the art of medicinal chemistry.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is 571-270-5863. The examiner can normally be reached 8:00-5:00 Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-071818. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614
Bbs

BONG-SOOK BAEK
Examiner, Art Unit 1614